Wiener lab.
Especialidades para Laboratorios Clínicos

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Section 6 – Summary

DEC 0 9 2002

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K023530 **"**

Introduction

According to the requirements of 21 CFR 862.1775, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

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Contact person: Viviana Cétola
Date Prepared: September 02, 2002

6-2 Device Name

Proprietary name: Wiener lab. Uricostat *enzimático* AA Líquida.
Common name: Uric acid test system
Classification name: Acid, uric, uricase (colorimetric)
Device Class I

6-3 Predicate Device

We claim substantial equivalence to the currently marketed Wiener lab. Uricostat *enzimático* AA test system (Cat. Nº 1840106).

6-4 Device Description

End point method.

The principle is based on the following reaction system:

$$\text{Uric Acid} + 2\,H_2O + O_2 \xrightarrow{\text{UOD}} \text{Allantoin} + H_2O_2 + CO_2$$

$$2\,H_2O_2 + \text{4-AP} + \text{3,5-SDH} \xrightarrow{\text{POD}} \text{red quinonimine}$$

The amount of uric acid is determined by measuring the absorbance of this pigment.

UOD: Uricase; POD: Peroxidase; 4-AP: 4-Aminophenazone; 3,5-DHS: 3,5-dichlorohydroxybenzenesulfonic acid, sodium salt.

6-5 Intended Use

The Wiener lab. Uricostat *enzimático* AA Líquida. test system is a quantitative in vitro diagnostic device intended to be used in the determination of uric acid in human sera and heparinized plasmas on both manual and automated systems. Measurements of serum uric acid, are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients under treatment with cytotoxic drugs.

6-6 Equivalencies and Differences

The Uricostat *enzimático* AA Líquida test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Uricostat *enzimático* AA test system.

The following table illustrates the similarities and differences between the Uricostat *enzimático* AA Líquida test system and the currently marketed Uricostat *enzimático* AA test system.

	Uricostat *enzimático* AA	**Uricostat *enzimático* AA Líquida**
Intended Use	Enzymatic method for the determination of uric acid in serum or urine.	Enzymatic method for the determination of uric acid in serum or plasma.
Test Principle	End point method. The analytical system is based on the following reaction: Uric Acid + 2 H_2O + O_2 ↓ UOD Allantoin + H_2O_2 + CO_2 2 H_2O_2 + 4-AP + 3,5-DHS ↓ POD red quinonimine The amount of uric acid is determined by measuring the absorbance of this pigment. UOD: Uricase; POD: Peroxidase; 4-AP: 4-Aminophenazone; 3,5-DHS: 3,5-dichlorohydroxybenzenesulfonic acid, sodium salt.	
Reagents	Standard: uric acid . Buffer: phosphates buffer. Enzymes: UOD – POD – DHS – 4-AP – Potassium Ferrocyanide.	Standard: uric acid . Reagent 1: Good buffer - DHS. Reagent 2: Good buffer - 4-AP – UOD – POD – Potassium Ferrocyanide.
Preparation of Working Reagent	Dissolution of an Enzyme vial in a Buffer bottle.	Reagents may be used separately or as **Monoreagent**, mixing 4 parts of Reagent 1 + 1 part of Reagent 2 .

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	Uricostat *enzimático* AA	**Uricostat *enzimático* AA Líquida**
Stability of Final Color	30 minutes.	
Wavelength of Reading	505 nm in spectrophotometer or 490-530 nm in photocolorimeter with green filter.	
Calibration	Single point.	
Linearity	20 mg/dl	
Within-run precision	Normal Control: CV = 1.75% Abnormal Control: CV = 1.78%	Normal Level Serum: CV = 2.21% High Level Serum: CV = 1.32%
Run-to-run precision	Normal Control: CV = 2.61% Abnormal Control: CV = 2.39%	Normal Level Serum: CV = 2.86% High Level Serum: CV = 1.90%

6-7 Conclusion Above mentioned data show substantial equivalency to the predicate device.

510(k) Number (if known): K023550

Device Name: Wiener lab.
URICOSTAT enzimático AA LÍQUIDA

Indications For Use:

The "Wiener lab. Uricostat *enzimático* AA Líquida" test system is a quantitative in vitro diagnostic device intended to be used in the determination of uric acid in human sera and heparinized plasmas on both manual and automated systems. Measurements of serum uric acid are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients under treatment with cytotoxic drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 9 2002

Dr. Viviana Cetola
QC/QA Manager
Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario - Argentina

Re: k023550
Trade/Device Name: Wiener Lab. Uricostat enzimatico AA Liquida
Regulation Number: 21 CFR § 862.1775
Regulation Name: Uric Acid, Uricase (Colorimetric)
Regulatory Class: I
Product Code: KNK
Dated: September 13, 2002
Received: October 22, 2002

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033550

Device Name: Wiener lab.
URICOSTAT ENZIMÁTICO AA LÍQUIDA

Indications For Use:

The "Wiener lab. Uricostat *enzimático* AA Líquida" test system is a quantitative in vitro diagnostic device intended to be used in the determination of uric acid in human sera and heparinized plasmas on both manual and automated systems. Measurements of serum uric acid are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients under treatment with cytotoxic drugs.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K033550